

REMARKS:

Applicant notes that the pending application has been moved to Art Unit 1615 and has been reassigned to Examiner Humera N. Sheikh. Applicant further notes that the request to rejoin method claims 46-63 upon allowance of the elected compositions claims 1-45 has been acknowledged.

• Status of the Claims

By this Response, claims 1, 3-5, 7, 46, 48-50, and 52 have been amended and claims 64-77 have been added. No new subject matter has been added by these amendments. Claims 1-45 and 64-72 are pending in the present application, claims 46-63 are withdrawn. Claims 73-77 are new and are directed towards the subject matter of the withdrawn claims. Should claims 73-77 be presumed withdrawn, Applicant specifically reserves the right to rejoin claims 73-77 pursuant to the rejoinder procedures set forth in MPEP §820.04, upon the allowance of appropriate elected claims.

• Claim Objections

In the Office Action dated June 16, 2006, the Examiner objected to claims 1-45 pursuant to 35 U.S.C. §112 as not being enabled based on their recitation of the word, prevention. Applicant has addressed this concern by removing the term, prevention, as suggested by the Examiner. Page 3, Line 4. As such, the claims are directed towards “[a] composition useful for the non-addictive treatment of an upper airway condition in a subject.” In accordance with its common meaning, the term treatment is understood to include pre-treatment and post-treatment, i.e., treatment of the upper airway condition before and/or after the condition it is apparent to the

subject, or the alleviation of symptoms before or after the symptoms are apparent to the subject.

• **Claim Rejections Pursuant to 35 U.S.C. §§ 102 and 103**

Claims 1, 2, 5, 6, 8-10, 13, 26, 29, 30, and 33-43 have been rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2002/0061281 of Osbakkan, et al. (“281 Publication”).

Claims 1, 2, 5, 6, and 8-43 have also been rejected pursuant to 35 U.S.C. §103(a) as being obvious in light of the ‘281 Publication.

Claims 3, 4, and 7 have been rejected pursuant to 35 U.S.C. §103(a) as being obvious in light of the ‘281 Publication in combination with U.S. Patent No. 5,698,558 to Gray.

Claims 44 and 45 have been rejected pursuant to 35 U.S.C. §103(a) as being obvious in light of the ‘281 Publication in combination with U.S. Patent No. 6,344,210 to Fust.

The Applicant has addressed these concerns by amended the claims, as set forth above, and by providing the remarks that follow.

Rejections Citing U.S. Patent Publication No. 2002/0061281 of Osbakken, et al.
(“281 Publication”)

This Response will now address the rejections based on the ‘281 Publication as an independent reference. Original claims 3 and 7 were not included in either the anticipation rejection or the obviousness rejection based on the ‘281 Publication. Claims 1, 2, and 10-43 have been amended to include the limitations of original claim 3. Claims 5, 6, 8, and 9 have been amended to include limitations from claim 7. As such, it is respectfully requested that rejection of the claims pursuant to §§102 and 103 based on the ‘281 Publication as an independent reference be withdrawn.

Rejections Citing the '281 Publication in Combination with Another Reference

Claimed Invention

Before addressing the remaining §103 rejections, Applicant believes it to be beneficial to review some of the features and advantages of the invention of the pending claims, as amended by this Response. Pending claim 1 and the claims depending therefrom are directed towards a composition for treating rhinitis. Rhinitis involves inflammation of the nasal passageways, and includes, for example, allergic rhinitis (e.g., resulting from allergens such as pollen, mold, animal dander, or certain foods), non-allergic rhinitis (e.g., resulting from strong odors, temperature changes, pregnancy, or microbial infection), and mixed rhinitis (combination of stimuli). Certain types of rhinitis can exist concurrently with a condition known as sinusitis; however, rhinitis should not be confused with sinusitis. Sinusitis involves inflammation of the *sinuses*, while rhinitis involves inflammation of the *nasal passageways*. The conditions are distinct and have distinct pathologies.¹

Prior to the invention, it had been recommended not to use systemic decongestant therapy on a long-term basis (e.g., longer than 4 to 5 days) due to risk of developing adverse side effects, such as addiction to the decongestants. The decongestant-containing composition of the pending claims was surprisingly found to alleviate congestion in subjects using the composition on a long term basis, without the subjects developing adverse side effects, i.e., addiction to the decongestant. As such, the pending claims are directed towards a composition for the *non-addictive* treatment of rhinitis, or pharyngitis, including a nasal decongestant, a corticosteroid,

¹ Certain of the pending claims are directed towards a composition for treating pharyngitis, which is a condition that is separate and distinct from sinusitis.

and an anticholinergic agent.

Certain dependant claims are directed towards compositions that additionally include an aromatic agent, e.g., camphor, eucalyptus, menthol. The aromatic agent creates the sensation for the subject of increased air flow through the nasal passageway, occurring substantially immediately after the composition is used. The perceived instantaneous relief creates an incentive for the subject to use the composition to affect treatment of rhinitis, i.e., promotes compliance.

Establishing a Prima Facie Case of Obviousness

The rejections that will be addressed below are obviousness-type rejections based on a combination of references. In order to establish a *prima facie* case of obviousness, three basic elements must be established: (1) there must be some suggestion or motivation, in the prior art, to combine the cited references; (2) there must be a reasonable expectation of success found in the prior art; and (3) the cited combination of references must teach or suggest each and every limitation of the claimed invention. See e.g., MPEP §§ 706.02 and 2142; In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In order to establish these elements, the PTO must provide an evidentiary basis for its position. In this regard, evidence from the prior art must be particularly pointed out, e.g., an express or implied teaching from the prior art that is particularly pointed out, or a convincing line of reasoning that is particularly provided with regard to each requisite element of the *prima facie* case. See e.g., MPEP §§ 706.02 and 2142; Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Rejections Citing '281 Publication in Combination with
U.S. Patent No. 5,698,558 to Gray ("'558 Patent")

Claims 3, 4, and 7 have been rejected pursuant to 35 U.S.C. §103(a) as being obvious in light of the '281 Publication in combination with the '558 Patent.

The '281 Publication describes compositions and methods for treating chronic sinusitis, which is "an inflammation of the membrane lining one or more paranasal sinuses ...[which] lasts longer than three weeks and often continues for months." See '281 Publication, Paragraph [0005]. The '281 Publication identifies causes for sinusitis, including "a viral cold or flu that infects the upper respiratory tract and causes obstruction...creat[ing] an environment that is hospitable for bacteria." See Paragraph [0007]. Various organisms can cause sinusitis, including bacteria, viruses, and, less commonly, fungi. See Paragraph [0009]. Sinusitis differs from rhinitis; it has distinct pathology and is a distinct condition. See e.g., '281 Publication, Paragraphs [0041] and [0054], indicating distinctions between the condition known as sinusitis and the condition known as rhinitis.

On the other hand, as described briefly above, pending claim 1 and the claims depending therefrom, are directed towards a *non-addictive* composition for treating *rhinitis*. Other embodiments of the claimed invention are directed towards a *non-addictive* composition for treating *pharyngitis*.

In order to meet the initial burden of persuasion for an obviousness case, the above-mentioned basic elements a *prima facie* case of obviousness must be established. The first basic element requires a showing that there is a suggestion or motivation in the prior art select and combine the cited references. See e.g., Abbott Laboratories v. Syntro Research, Inc., 334 F.3d 1343 (Fed. Cir. 2003); Karsten Mfg. Corp. v. Cleveland Gulf Co., 242 F.3d 1376, 1385 (Fed. Cir. 2001); Northern Telecom v. Datapoint Corp., 908 F.2d 931, 934 (Fed. Cir. 1990) ("It

is insufficient that the prior art disclosed the components of the patented device either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor.”). Such a showing must have evidentiary support, particularly pointed out and taken from the prior art.

The second basic element requires a showing that there is a reasonable expectation of success found in the prior art, as determined from the vantage point of one of ordinary skill in the art at the time the invention was made. See e.g. Amgen, inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1209, 18 USPQ 1016, 1023 (Fed. Cir. 1991). Such a showing must have evidentiary support, particularly pointed out and taken from the prior art.

In the rejection based on the combination of the ‘281 Publication and the ‘588 Patent, the Examiner addresses these two elements of an obviousness case with the following statement: “One of ordinary skill in the art would have been motivated [to combine the references] with a reasonable expectation of success because [the ‘558 Patent] explicitly teaches that the compositions comprising cetirizine are effective for treating (allergic) rhinitis, as well as symptoms arising from (allergic) rhinitis.” Page 10, Lines 20-21 through Page 11, Lines 1-5 (emphasis provided). This statement merely provides information about the teaching of the ‘558 Patent; it does not provide evidence to establish any motivation to combine the ‘558 Patent and the ‘281 Publication. In other words, there is not any convincing line of reasoning that is provided to explain of how an “explicit teach[ing in the ‘558 Patent] of a composition comprising cetirizine for treatment of allergic rhinitis” would motivate one of ordinary skill in the art to select the ‘558 Patent, then select the ‘281 Publication, then combine them to create the claimed invention. Likewise, there is not any convincing line of reasoning that is provided to explain how this teaching of the ‘558 Patent would have provided a reasonable expectation of

success.

Indeed, there is no apparent reason why a teaching in a first reference of a treatment of allergic rhinitis, a condition associated with inflammation of the nasal passageway generally resulting from exposure to allergens, would motive one to select a second reference that that is directed towards treatment of chronic sinusitis, a condition associated with long-standing inflammation of the sinuses generally resulting from a microbial infection (i.e., non-allergic), and then motive one to combine the two references to achieve the claimed invention with a reasonable expectation of success.

Because the requisite motivation to combine the references is lacking, and because the requisite showing of a reasonable expectation of success is lacking, the obviousness rejection is believed to be improper.

Furthermore, the teachings of the '281 Publication would dissuade one of ordinary skill in the art from modifying the '281 Publication to create the claimed invention. Indicative of a lack of the requisite motivation to modify with a reasonable expectation of success is a reference that teaches away from the claimed invention. A proposed modification is also inappropriate where the modification renders the prior art reference inoperable for its intended purpose.

The '281 Publication describes an apparatus for delivering anti-infective particles having a mass median aerodynamic diameter (MMAD) of about 1-5 microns. See Paragraph [0081]. The Publication further describes the benefit of using a surfactant to increase the deposition, retention, and penetration of anti-infectives.” See Paragraph [0081]. It is “critical” to the compositions of the '281 Publication that a particular surface tension and particle size be delivered, to allow for the particles to enter the sinuses, the site of the inflammation and infection that defines the condition of sinusitis. See Paragraph [0092]. Specific delivery of a topical

treatment agent to the sinuses would serve to affect treatment of sinusitis, but it would not effectively treat rhinitis because it would not be acting at the appropriate site of the rhinitis-associated inflammation. In this regard, the '281 Publication teaches away from compositions for treating rhinitis.

Furthermore, the very device that is described as being so useful for practicing the method of the '281 Publication, which delivers the composition in particles of a particular surface tension and particle size to the sinuses, produces an air flow capable of causing non-allergic rhinitis in susceptible subjects. By modifying the '281 Publication to avoid actually creating rhinitis stimuli, and to treat rhinitis, the critical teachings of the '281 Publication that allow for the beneficial delivery of treatment agent to the sinuses would be thwarted. For these additional reasons, it is believed that the rejection is improper.

Therefore, it is respectfully requested that the rejection based on the '281 Publication in light of the '588 Patent be withdrawn.

*Rejections Citing '281 Publication in Combination with
U.S. Patent No. 6,344,210 to Fust ("'210 Patent")*

Claims 44 and 45 have been rejected pursuant to 35 U.S.C. §103(a), as being obvious in light of the '281 Publication in combination with the '210 Patent.

As mentioned above, a *prima facie* case of obviousness requires three basic elements to be established. As also mentioned above, these elements include: a suggestion or motivation, in the prior art, to select and combine the cited references; and a reasonable expectation of success found in the prior art. In the rejection based on the combination of the '281 Publication and the '210 Patent, the Examiner addresses these two elements of an obviousness case with the following statement: "One of ordinary skill in the art would have been motivated [to combine

the references] with a reasonable expectation of success because [the ‘210 Patent] explicitly teaches that the freshening ingredients of the composition leaves the nose and sinuses feeling cleansed, cleared and refreshed with a minty after-taste, thus eliminating and masking objectionable odors.” Page 12, Lines 14-19 (emphasis provided). This statement merely provides information about the teaching of the ‘210 Patent; it does not provide evidence to establish any motivation to combine the ‘210 Patent and the ‘281 Publication. In other words, there is not any convincing line of reasoning that is provided to explain of how an “explicit teach[ing in the ‘210 Patent] that the freshening ingredients of the composition leaves the nose and sinuses feeling cleansed...with a minty after-taste” would motivate one of ordinary skill in the art to select the ‘210 Patent, then select the ‘281 Publication, then combine them to create the claimed invention. Likewise, there is not any convincing line of reasoning that is provided to explain how this teaching of the ‘210 Patent would have provided a reasonable expectation of success.

Indeed, there is no apparent reason why a teaching in a first reference of a composition for creating a refreshed sensation and minty after-taste in the nose and sinuses, a cosmetic or hygienic action, would motive one to select a second reference that that is directed towards treating chronic sinusitis, a condition associated with long-standing inflammation of the sinuses generally resulting from a microbial infection, and then motive one to combine the two references to achieve the claimed invention with a reasonable expectation of success.

It is additionally noted that the requisite evidentiary support for the third basic element necessary to establish a *prima facie* case of obviousness has not been supplied. The third basic element requires a showing that the cited combination of references teaches or suggests each and every limitation of the claimed invention. See e.g., In re Wilson, 424 F.2d 1382, 1385, 165

USPQ 494, 496 (CCPA 1970). Claims 44 and 45 are directed towards a composition for treating rhinitis, which composition includes an aromatic agent. The '281 Publication fails to teach compositions for treating rhinitis and fails to teach compositions including an aromatic agent. The '210 Patent is directed towards a composition for "freshening sinus cavities," not a composition directed towards the treatment of rhinitis.² As such, the combination of the references fails to teach or suggest each and every limitation of the claimed invention.

Because the requisite motivation to combine the references is lacking, because the requisite showing of a reasonable expectation of success is lacking, and because the requisite teaching or suggestion of each and every limitation of the claimed invention is lacking, the obviousness rejection is believed to be improper.

Furthermore, for the reasons set forth above with regard to the '218 Publication in light of the '558 Patent, the teachings of the '281 Publication would dissuade one of ordinary skill in the art from modifying the '281 Publication to create the claimed invention with a reasonable expectation of success. As such, for these additional reasons, it is believed that the rejection is improper.

Therefore, it is respectfully requested that the rejection based on the '281 Publication in light of the '210 Patent be withdrawn.

² The Office Action cites the '210 Patent, Column 2, Lines 42-52 for the proposition that the "compositions [of the '210 patent] are especially effective for persons with sinusitis and rhinitis." This proposition is inaccurate and/or misleading. Column 2, Lines 42-53 are taken from the "Background of the Invention" of the '210 Patent and do not in any way describe a composition, effective or otherwise, for treating rhinitis, or a composition, effective or otherwise, for treating sinusitis. The cited paragraph is devoid of any mention of a compound, method, device, etc. for treating any condition.

In light of the foregoing amendments and remarks, Applicant respectfully requests allowance of all claims now pending in this Application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mandy Decker", written over the printed name.

Mandy Wilson Decker

Reg. No. 53,781

STITES & HARBISON, PLLC

400 W. Market Street

Louisville, Kentucky 40202-3352

Phone (502) 587-3400

Facsimile (502) 587-6391

AL130:00AL1:548389:4:LOUISVILLE